EXHIBIT 58

[redacted]

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (GBW)
SAREPTA THERAPEUTICS, INC., and THE UNIVERSITY OF WESTERN AUSTRALIA Counterclaimants v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Counterclaim Defendants.	

NIPPON SHINYAKU CO. LTD. AND NS PHARMA, INC.'S NONINFRINGEMENT CONTENTIONS

Pursuant to Paragraph 3(g) of the of the Scheduling Order (D.I. 143), Plaintiff/Counterclaim Defendant Nippon Shinyaku Co. Ltd. and Counterclaim Defendant NS Pharma, Inc. (collectively "NS") provide the following noninfringement contentions for each asserted claim to Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc. ("Sarepta"). These Noninfringement Contentions disclose the current bases for Defendants' contentions regarding noninfringement.

NS provides this disclosure based on the information and evidence available to it at this time, without the benefit of full discovery. NS therefore reserves its right to make any modifications, additions, deletions, or supplementations to this disclosure as additional evidence and information become available, or as is otherwise appropriate and permissible.

I. THE UWA PATENTS

These contentions relate to the claims that Sarepta asserts in its June 22, 2023 Infringement Contentions against NS U.S. Patent Nos. 9,994,851 ("the '851 patent"); 10,227,590 ("the '590 patent"); and 10,266,827 ("the '827 patent") (collectively, "the UWA Patents"). Sarepta's infringement contentions assert claims 1 and 2 of the '851 Patent, claims 1 and 2 of the '590 Patent, and claims 1 and 2 of the '827 Patent (collectively, the "Asserted Claims").

To the extent Sarepta is granted leave to amend its contentions to add any claims from these or other patents, NS will serve supplemental contentions directed at any such additional claims.

These contentions are based on NS's present understanding of the asserted claims and/or claim constructions that may be discerned in light of Sarepta's allegations of infringement and apparent interpretation of the asserted claims. NS's contentions are not, and should in no way be interpreted as, admissions, suggestions, or adoptions of any particular claim scope or construction. NS reserves the right to amend or supplement its contentions to address any further information provided by the Court or Sarepta regarding the meaning or scope of the terms of the asserted claims.

II. SAREPTA'S INFRINGEMENT CONTENTIONS

Sarepta has claimed that "[b]y making, using, selling, offering to sell, and/or importing Viltepso® (viltolarsen), NS **directly and indirectly** infringes the asserted claims of the Wilton Patents [i.e., the UWA patents]." Final Infringement Contentions at 1-2 (**emphasis added**).

Sarepta further claims that "[a] physician or healthcare provider administering NS's Viltepso® (viltolarsen) product in accordance with its approved labeling will directly infringe, either literally or under the doctrine of equivalents, each asserted claim of the Wilton Patents, in violation of 35 U.S.C. § 271(a)." *Id.* at 2.

Sarepta further claims that "NS actively induces and intentionally encourages, aids, and abets the manufacture, offer for sale, sale, import, and use of Viltepso . . . in violation of 35 U.S.C. § 271(b)." *Id.*

Sarepta further claims that "NS contributes to, and will continue to contribute to, the direct infringement of the asserted claims of the Wilton Patents . . . in violation of 35 U.S.C. § 271(c)." *Id.*

Sarepta further claims that "NS's infringement is also willful." *Id.* at 3.

Accordingly, Sarepta's infringement contentions assert that NS directly, indirectly, and willfully infringes each of claims 1 and 2 of the '851 Patent, claims 1 and 2 of the '590 Patent, and claims 1 and 2 of the '827 Patent.

III. NS'S NONINFRINGEMENT CONTENTIONS

For the reasons set forth in detail below, Sarepta's infringement contentions are without merit. NS reserves the right to supplement or amend these contentions as discovery in this case proceeds.

A. Sarepta Has Failed to Meet Its Burden to Demonstrate Infringement By A Preponderance of the Evidence

It is Sarepta's burden to prove that NS infringes each and every asserted claim of the UWA Patents by a preponderance of the evidence. *Imhaeuser v. Buerk*, 101 U.S. 647, 662 (1879) ("[T]he burden to prove infringement never shifts if the charge is denied in the plea or answer."); *Accord Jazz Photo Corp. v. Int'l Trade Comm'n.*, 264 F.3d 1094, 1102 (Fed. Cir. 2001) ("The initial burden is upon the complainant to establish its cause of action, here patent infringement; the patentee must present evidence sufficient to establish that one or more patent claims are infringed."); *Nutrinova Nutrition Specialities & Food Ingredients GmbH v. Int'l. Trade Comm'n.*, 224 F.3d 1356, 1359 (Fed. Cir. 2000) ("As a general proposition, the law places the burden of

proving infringement on the patentee who alleges it."); *Centricut, L.L.C. v. Esab Group, Inc.*, 390 F.3d 1361, 1367 (Fed. Cir. 2004) ("The patentee has the burden of proving infringement by a preponderance of the evidence."); *Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) ("Infringement requires proof by a preponderance of the evidence."); *SRI Int'l. v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1123 (Fed. Cir. 1985) ("The patentee bears the burden of proving infringement by a preponderance of the evidence.").

Sarepta has identified its evidence alleging that NS directly, indirectly, and willfully infringes each of claims 1 and 2 of the '851 Patent, claims 1 and 2 of the '590 Patent, and claims 1 and 2 of the '827 Patent. However, this evidence in insufficient to demonstrate that NS directly, indirectly, or willfully infringes any of the Asserted Claims. Accordingly, it is NS's contention that Sarepta has failed to meet its burden to demonstrate infringement of any of the Asserted Claims by a preponderance of the evidence.

NS may rely upon Sarepta's admissions made in pleadings, responses to interrogatories and requests for admission, as further evidence that Sarepta has failed to meet its burden to demonstrate infringement of any of the Asserted Claims by a preponderance of the evidence. NS likewise notes that depositions are ongoing, and that it may rely upon the testimony of Sarepta's, UWA's, Nippon Shinyaku's, and NS Pharma's witnesses as yet further evidence that Sarepta has failed to meet its burden to demonstrate infringement of any of the Asserted Claims by a preponderance of the evidence. NS further states that it may rely on expert reports and expert testimony of both Sarepta and NS experts as further evidence that Sarepta has failed to meet its burden to demonstrate infringement of any of the Asserted Claims by a preponderance of the evidence. NS reserves the right to supplement or amend these contentions as discovery in this case proceeds.

B. NS Does Not Infringe Any Valid Asserted Claim Because Each Asserted Claim of the UWA Patents is Invalid

As set forth in NS's Invalidity Contentions, served on July 11, 2023, each of the Asserted Claims of the UWA Patents is invalid. Accordingly, NS does not and cannot infringe any valid claim of the UWA Patents. As set forth in NS's Invalidity Contentions, NS may rely upon Sarepta's admissions made in pleadings, responses to interrogatories and requests for admission, as evidence that NS does not and cannot infringe any valid claim of the UWA Patents. NS likewise notes that depositions are ongoing, and that it may rely upon the testimony of Sarepta's, UWA's, Nippon Shinyaku's, and NS Pharma's witnesses as yet further evidence that NS does not and cannot infringe any valid claim of the UWA Patents. NS further states that it may rely on expert reports and expert testimony of both Sarepta and NS experts as further evidence that NS does not and cannot infringe any valid claim of the UWA Patents. NS reserves the right to supplement or amend these contentions as discovery in this case proceeds.

C. The Manufacture, Use, Sale, Offer for Sale, or Importation of Viltepso Does Not Infringe Any Asserted Claim Because the Base Sequence of Viltepso Does Not Comprise at Least 12 Consecutive Bases of SEQ ID NO: 195

Each of claims 1 and 2 of the '851 Patent, claims 1 and 2 of the '590 Patent, and claims 1 and 2[1] of the '827 Patent require an "antisense oligonucleotide . . . comprising a base sequence" and **"wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195)."** (emphasis added).

Sarepta has claimed that "[b]y making, using, selling, offering to sell, and/or importing Viltepso® (viltolarsen), NS **directly and indirectly** infringes the asserted claims of the Wilton Patents [i.e., the UWA patents]." Final Infringement Contentions at 1-2 (**emphasis added**).

[1] Claim 2 does not expressly recite this language, but claim 2 depends from claim 1, which does recite the language.

[redacted] *See e.g.,* NS00035784 at -790; NS00035807 at -813; NS00067092 at -098; NS's Responses and Objections to Sarepta's First Set of Request for Admission at 8 ("[redacted]"). [redacted] *Id.*; *see also* NS's Responses and Objections to Sarepta's First Set of Request for Admission at 9 ("[redacted]"). [redacted]

[redacted]

Yet, Sarepta argued and the Court confirmed that the phrase "in which uracil bases are thymine bases" does not modify the preceding phrase, but modifies the antisense oligonucleotide as a whole. *See* Claim Construction Memorandum Opinion, DI 248 at 25-29. In analyzing the term "in which uracil bases are thymine bases," the Court first pointed to the grammatical structure of the claim language:

> The plain language of the claim uses commas to set off each "wherein" and "in which" clause, suggesting that **the "in which uracil bases are thymine bases" term modifies the antecedent subject "an antisense oligonucleotide."** To be sure, the claim also uses serial commas before every "wherein" and "in which" clause, which generally suggest, as a matter of grammar, a listing of individual, independent items in a series. . . . Moreover, **if the "in which uracil bases are thymine bases" term modified the sequence of bases immediately preceding it, i.e., SEQ ID NO: 195, as NS contends, then there would be no reason the patentee used a comma to separate the "in which uracil bases are thymine bases" term from the rest of the claim language**.

Id. at 26-27. In addition, the Court pointed to the prosecution history as evidence that "the applicant identified **'uracil bases [being] thymine bases' as a feature of the claimed antisense oligonucleotide rather than a feature of the preceding 'base sequence' limitation**." *Id.* at 27-28.

In view of the entirety of the evidence, the Court concluded that "each listed element, including 'uracil bases are thymine bases,' **independently modifies** the antecedent subject 'an antisense oligonucleotide' as a whole rather than a feature of the preceding 'base sequence' limitation." *Id.* at 28. In doing so, the Court adopted Sarepta's proposed construction that it argued for throughout the claim construction process. Sarepta cannot argue for a different construction now.

The result of the Court's construction is that the claimed "antisense oligonucleotide" must meet two "independent" limitations:

- The antisense oligonucleotide must include a base sequence "wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195)."
- "[T]he antisense oligonucleotide has thymine bases instead of uracil bases." DI 249 at 2.

[redacted]

While Sarepta has included general allegations that NS may infringe under the doctrine of equivalents, Sarepta has not provided any substantive contentions related to any allegations under the doctrine of equivalents. *See e.g.,* Final Infringement Contentions at Exhibits A, B and C. Sarepta's failure to provide any substantive contentions related to infringement under the doctrine of equivalents demonstrates that Sarepta cannot meet its burden to prove infringement as a matter of law.

Nonetheless, any contention that NS infringes under the doctrine of equivalents cannot succeed due to the dedication-disclosure doctrine. "When a patentee discloses subject matter but does not claim it, the patentee dedicates the unclaimed subject matter to the public and cannot recapture it through the doctrine of equivalents." *Indivior Inc. v. Dr. Reddy's Labs., S.A.,* 930 F.3d 1325, 1346 (Fed. Cir. 2019) (citing *Johnson & Johnston Assoc. v. R.E. Serv. Co.,* 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc)). To determine whether the disclosure-dedication doctrine applies in a given case, the court asks whether the specification discloses unclaimed subject matter with "such specificity that one of ordinary skill in the art could identify the subject matter that had been

disclosed and not claimed." *Eagle Pharms. Inc. v. Slayback Pharma LLC,* 958 F.3d 1171, 1175 (Fed. Cir. 2020) (quoting *PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc.,* 355 F.3d 1353, 1360 (Fed. Cir. 2004)). "If the court concludes that the inventor dedicated an alleged equivalent to the public, the patent owner cannot prevail on its doctrine of equivalents infringement claim based on that equivalent." *Eagle Pharms*., 958 F.3d at 1175.

Here, any alleged equivalent has been disclosed in the patent, dedicated to the public, and cannot be the basis of a claim under the doctrine of equivalents. Here, the alleged equivalent limitation would require an antisense oligonucleotide comprising a base sequence "wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195)" except wherein the uracil bases of SEQ ID NO: 195 are replaced with thymine bases instead. However, this "equivalent" is expressly disclosed in the specification of the UWA Patents at Table 1A:

TABLE 1A-continued

Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA- like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T".

SEQ ID	SEQUENCE	NUCLEOTIDE SEQUENCE (5'-3')
192	H53A(+39+62)	CUG UUG CCU CCG GUU CUG AAG GUG
193	H53A(+39+69)	CAU UCA ACU GUU GCC UCC GGU UCU GAA GGU G
194	H53D(+14-07)	UAC UAA CCU UGG UUU CUG UGA
195	H53A(+23+47)	CUG AAG GUG UUC UUG UAC UUC AUC C

See e.g., '851 Patent at Col. 19 (reciting SEQ ID NO: 195 with uracil bases, but explaining that "these U[racil] bases may be shown as "T[hymine]" bases instead). Since any alleged infringing

"equivalent" has been dedicated to the public, NS cannot infringe any claim of the UWA Patents under the doctrine of equivalents.

In support of its positions, NS may rely upon Sarepta's admissions made in pleadings, responses to interrogatories and requests for admission, as evidence that NS does not infringe the UWA Patents because Viltepso does not include at least 12 consecutive bases of SEQ ID NO: 195 either literally or under the doctrine of equivalents. NS likewise notes that depositions are ongoing, and that it may rely upon the testimony of Sarepta's, UWA's, Nippon Shinyaku's, and NS Pharma's witnesses as yet further evidence that NS does not infringe the UWA Patents because Viltepso does not include at least 12 consecutive bases of SEQ ID NO: 195 either literally or under the doctrine of equivalents. NS further states that it may rely on expert reports and expert testimony of both Sarepta and NS experts as further evidence that NS does not infringe the UWA Patents because Viltepso does not include at least 12 consecutive bases of SEQ ID NO: 195 either literally or under the doctrine of equivalents. NS reserves the right to supplement or amend these contentions as discovery in this case proceeds.

D. NS Does Not Directly Infringe Claims 1 and 2 of the '827 Patent Because It Does Not Administer an Antisense Oligonucleotide to a Patient

Claims 1 and 2[2] of the '827 Patent require "administering to the patient an antisense oligonucleotide." Sarepta has claimed that "[b]y making, using, selling, offering to sell, and/or importing Viltepso® (viltolarsen), NS **directly** and indirectly infringes the asserted claims of the Wilton Patents [i.e., the UWA patents]." Final Infringement Contentions at 1-2 (**emphasis added**). However, in setting forth its specific evidence in its claim charts Sarepta has not identified substantive contentions that NS directly infringes claims 1 and 2 of the '827 Patent by

[2] Claim 2 does not expressly recite this language, but claim 2 depends from claim 1, which does recite the language.

administering Viltepso to a patient. *See id.* at Exhibit C. Sarepta's failure to provide any substantive contentions related to direct infringement demonstrates that Sarepta cannot meet its burden to prove direct infringement as a matter of law. In fact, NS does not directly infringe the claims of the '827 Patent because it does not "administer" an antisense oligonucleotide to a patient.

In support of its positions, NS may rely upon Sarepta's admissions made in pleadings, responses to interrogatories and requests for admission, as evidence that NS does not directly infringe the claims of the '827 Patent because it does not "administer" an antisense oligonucleotide to a patient. NS likewise notes that depositions are ongoing, and that it may rely upon the testimony of Sarepta's, UWA's, Nippon Shinyaku's, and NS Pharma's witnesses as yet further evidence that NS does not directly infringe the claims of the '827 Patent because it does not "administer" an antisense oligonucleotide to a patient. NS further states that it may rely on expert reports and expert testimony of both Sarepta and NS experts as further evidence that NS does not directly infringe the claims of the '827 Patent because it does not "administer" an antisense oligonucleotide to a patient. NS reserves the right to supplement or amend these contentions as discovery in this case proceeds.

E. NS Does Not Indirectly Infringe Any Asserted Claim Because It Lacks The Requisite Knowledge

Indirect infringement, whether induced infringement under 35 U.S.C. § 271(b) or contributory infringement under 35 U.S.C. § 271(c), requires "knowledge of the patent in suit and knowledge of patent infringement." *See Commil USA, LLC v. Cisco Sys.*, 575 U.S. 632 (2015) (citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964)). Here, NS does not have the requisite knowledge of patent infringement necessary to induce or contribute to the infringement of the UWA Patents.

First, Sarepta provides contentions only that NS was "aware" of the UWA Patents prior to the filing of this lawsuit. *See e.g.,* Final Infringement Contentions at Exhibit A, p. 9. General

awareness of the UWA patents is insufficient to establish the requisite scienter necessary for induced or contributory infringement. [redacted] *See* Section C, *supra*. This good faith belief in noninfringement negates the necessary scienter required to demonstrate induced or contributory infringement.

In support of its positions, NS may rely upon Sarepta's admissions made in pleadings, responses to interrogatories and requests for admission, as evidence that NS does not indirectly infringe the UWA patents because it lacks the requisite scienter for induced or contributory infringement. NS likewise notes that depositions are ongoing, and that it may rely upon the testimony of Sarepta's, UWA's, Nippon Shinyaku's, and NS Pharma's witnesses as yet further evidence that NS does not indirectly infringe the UWA patents because it lacks the requisite scienter for induced or contributory infringement. NS further states that it may rely on expert reports and expert testimony of both Sarepta and NS experts as further evidence that NS does not indirectly infringe the UWA patents because it lacks the requisite scienter for induced or contributory infringement. NS reserves the right to supplement or amend these contentions as discovery in this case proceeds.

F. NS Does Not Willfully Infringe Any Asserted Claim

Willful infringement requires evidence that NS's alleged infringement was "wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1932 (2016). Sarepta claims that "NS's infringement is also willful." Final Infringement Contentions at 3. However, NS's activity does not support a finding of willful infringement.

First, the first of the UWA Patents was not filed until September 14, 2017. *See* '851 Patent. NS's development of Viltepso predated the filing of the UWA Patents by a number of years. *See, e.g.*, NS's Objections and Responses to Interrogatory No. 1, including all supplements thereto and documents cited therein. NS had already identified viltolarsen and begun developing Viltepso long before it had any awareness of the UWA Patents. *Id.* This development timeline demonstrates that NS's actions were not "wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate."

Second, Sarepta provides contentions only that NS was "aware" of the UWA Patents prior to the filing of this lawsuit. *See e.g.*, Final Infringement Contentions at Exhibit A, p. 9. General awareness of the UWA patents is insufficient to establish the requisite scienter necessary for willful infringement. [redacted] *See* Section C, *supra*. This good faith belief in noninfringement negates the necessary scienter required to demonstrate willful infringement.

Third, as set forth in NS's Invalidity Contentions, served on July 11, 2023, NS has had and continues to have a good faith belief that each of the Asserted Claims of the UWA Patents is invalid. NS's good faith belief in the invalidity of the UWA Patents negates the necessary scienter required to demonstrate willful infringement.

In support of its positions, NS may rely upon Sarepta's admissions made in pleadings, responses to interrogatories and requests for admission, as evidence that NS does not willfully infringe the UWA Patents. NS likewise notes that depositions are ongoing, and that it may rely upon the testimony of Sarepta's, UWA's, Nippon Shinyaku's, and NS Pharma's witnesses as yet

further evidence that NS does not willfully infringe the UWA Patents. NS further states that it may rely on expert reports and expert testimony of both Sarepta and NS experts as further evidence that NS does not willfully infringe the UWA Patents. NS reserves the right to supplement or amend these contentions as discovery in this case proceeds.

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MORGAN, LEWIS & BOCKIUS

/s/Amy M. Dudash

Amy M. Dudash (DE Bar No. 5741)
1201 N. Market Street
Suite 2201
Wilmington, Delaware 19801
Telephone: 302.574.3000
Fax: 302.574.3001
amy.dudash@morganlewis.com

Attorneys for Plaintiff/Counterclaim Defendant Nippon Shinyaku Co., Ltd. and Counterclaim Defendant NS Pharma, Inc.

Amanda S. Williamson (admitted *pro hac vice*)
Christopher J. Betti (admitted *pro hac* vice)
Krista V. Venegas (admitted *pro hac* vice)
Wan-Shon Lo (admitted *pro hac* vice)
Maria E. Doukas (admitted *pro hac vice*)
Zachary Miller (admitted *pro hac vice*)
Guylaine Haché (admitted *pro hac vice*)
Michael T. Sikora (admitted *pro hac vice*)
110 N. Wacker Drive, Ste 2800
Chicago, IL 60601
Telephone: 312.324.1000
Fax: 312.324.1001
amanda.williamson@morganlewis.com
christopher.betti@morganlewis.com
krista.venegas@morganlewis.com
shon.lo@morganlewis.com
maria.doukas@morganlewis.com
zachary.miller@morganlewis.com
guylaine.hache@morganlewis.com
michael.sikora@morganlewis.com

Eric Kraeutler (admitted *pro hac vice*)
Alison Patitucci (admitted *pro hac vice*)
1701 Market Street
Philadelphia, PA 19103
Telephone: 215.693.5000
Fax: 215.963.5001
eric.kraeutler@morganlewis.com
alison.patitucci@morganlewis.com